

REMARKS

Interview Summary

Applicants' representative thank Examiner Allen for the personal interview conducted on April 16, 2008. The Interview Summary highlights the main points discussed during the Interview. The Interview dealt mainly with the issues of what claim language was either supported by or not supported by the specification. The claim amendments presented herein and the new claims presented herein are believed to be fully supported by the present specification and thus should overcome the outstanding rejections.

Claim Amendments

Claim 9 has been amended and claims 1-8 and 10-22 have been cancelled. New claims 23-41 (which are directed to the elected invention) have been added. Thus, claims 9 and 23-41 are pending and ready for further action on the merits. Support for the various amendments to claim 9 and for the new claims is described below.

9. A screening method for ~~an anti-diabetic substances~~ comprising the steps of:

bringing a candidate substance to be screened into contact with a protein represented by the following (a) or (b):

(a) a protein consisting of the amino acid sequence represented by SEQ ID NO: 2 which is capable of interacting with a thiazolidine derivative; [page 10, lines 3-16 and page 14, lines 23-25] or

(b) a protein consisting of an amino acid sequence derived from the amino acid sequence represented by SEQ ID NO: 2 with the deletion, substitution, addition, or insertion of one or plural to thirty amino acids **[page 9, line 19]** ~~and interacting with the antidiabetic, wherein said protein retains the capability to interact with a thiazolidine derivative;~~ **[page 6, lines 1-5 and page 9, lines 14-18]** and

detecting screening for the presence or absence of any interaction between the candidate substance and the protein represented by (a) or (b) **[page 14, lines 26-28]**.

23. (New) **[see support cited above in claim 9]**.

24. (New) A screening method according to claim 9, wherein said candidate substance is a low molecular weight compound **[page 15, lines 1-2]**.

25. (New) A screening method according to claim 9, wherein said candidate substance is a protein **[page 15, lines 1-2]**.

26. (New) A screening method according to claim 23, wherein said candidate substance is a low molecular weight compound **[page 15, lines 1-2]**.

27. (New) A screening method according to claim 23, wherein said candidate substance is a protein **[page 15, lines 1-2]**.

28. (New) A screening method according to claim 9, wherein said protein is immobilized on a substrate and said candidate substance is brought into contact with said immobilized protein in order to measure the capability of said candidate substance to interact with said protein **[Example 1]**.

29. (New) A screening method according to claim 23, wherein said protein is immobilized on a substrate and said candidate substance is brought into contact with said immobilized protein in order to measure the capability of said candidate substance to interact with said protein [Example 1].

30. (New) A screening method according to claim 28, wherein said substrate is a chip [page 15, lines 3-20].

31. (New) A screening method according to claim 29, wherein said substrate is a chip [page 15, lines 3-20].

32. (New) A screening method according to claim 9, wherein said thiazolidine derivative is pioglitazone [page 6, lines 8-9].

33. (New) A screening method according to claim 23, wherein said thiazolidine derivative is pioglitazone [page 6, lines 8-9].

34. (New) A screening method according to claim 32, wherein said screening is performed by surface plasmon resonance [page 15, 2nd paragraph and Example 1].

35. (New) A screening method according to claim 33, wherein said screening is performed by surface plasmon resonance [page 15, 2nd paragraph and Example 1].

36. (New) A screening method according to claim 9, wherein said protein is protein (b) and wherein said deletion, substitution, addition or insertion is of one to ten amino acids [page 9, line 19].

37. (New) A screening method according to claim 9, wherein said protein is protein (b) and wherein said deletion, substitution, addition or insertion is of one to five amino acids [page 9, lines 19-20].

Support for the remaining claims is believed to be self-explanatory.

The Rejection Under 35 U.S.C. § 112, first paragraph (enablement)

Claims 9-12 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. One of the fundamental issues in this rejection appears to be the Examiner's concern that the claimed invention is not necessarily capable of determining if a "candidate substance" is capable of performing as an "antidiabetic". It is respectfully submitted that it is not necessary for the claimed invention to conclusively establish that the candidate substance is an antidiabetic substance since the claimed method is only a "screening method". In the course of development of an antidiabetic, additional testing would typically be done in order to meet FDA regulations. However, in an effort to advance prosecution of the application, the term "antidiabetic" has been removed from the claims. Claim 9 now merely requires determining whether the candidate substance interacts with protein (a) or (b), which proteins are substances the interact with a thiazolidine derivative (which includes known antidiabetic substances) and claims 32-35 and 39 indicate that the thiazolidine substance is pioglitazone (a well known antidiabetic substance). New claims 40 and 41 indicate that the candidate substance is one which has not yet been determined to be an antidiabetic. This is consistent with the description in the present specification where a number of compounds with unknown antidiabetic activity were screened.

The Examiner has questioned "what biological property must be retained by the mutated protein". The above discussed amendments indicate that the property to be retained by the candidate substance is the ability to interact with a thiazolidine substance, such as pioglitazone. It must be remembered that the present invention is a screening assay and is not meant to be

conclusive evidence of the ability of a substance to be useful as an antidiabetic substance. This is the province of the FDA, not the USPTO.

It is believed that the above-discussed amendments to the claims, taken together with the accompanying remarks, overcome this rejection.

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 9-12 have been rejected under 35 U.S.C. § 112, second paragraph, for a number of reasons. Regarding the correspondence between the preamble of the claim and the final step, it claim 9 has been amended so that the final step is consistent with the preamble. The preamble recites a “screening method...” and the final step is “screening for ...”. Thus, there is no inconsistency between the preamble and the final step of the claim. It is believed that the remaining issues raised in this rejection have also been addressed by the above-discussed amendments to the claims, taken together with the accompanying remarks made above in relation to the rejection under 35 U.S.C. § 112, first paragraph.

Conclusion

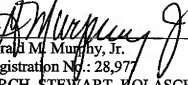
Applicant's have made a sincere effort to place this application into condition for allowance. If there are any amendments that can be made in order to place this application into condition for allowance, the Examiner is requested to contact Monique T. Cole, (Reg. No. 60,154), at the phone number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

Dated:

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Respectfully submitted,

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